April 4, 2003

VIA U.S. MAIL AND VIA ELECTRONIC SUBMISSION

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Docket No. 02N-0278
Prior Notice of Imported Food Under the Bioterrorism Act of 2002
FDA Proposed Rule

Dear Sir or Madam:

Nutraceutical Corporation (Nutraceutical) submits the following comments on the above-referenced Food and Drug Administration (FDA) proposal to implement the prior import notice provisions of the Public Health Security and Bioterorrism Preparedness and Response Act of 2002. See 68 Fed. Reg. 5428 (Feb. 3, 2003).

1. Confidentiality of contents. FDA has proposed that prior import notices include product identity information such as the name of the manufacturer and grower. Because of the nature of the dietary supplement industry, the names of parties involved in growing, sourcing and manufacturing natural products such as herbs are typically viewed by participants in the industry as confidential information. The prior import notice proposal contains no provision that the information submitted in prior notices will be considered and treated as confidential by FDA under the Freedom of Information Act. By contrast, the food facility registration proposal expressly provides that FDA will regard all registration information that would disclose the identity or location of an establishment as not subject to disclosure under FOIA except for information that was previously disclosed to the public. 68 Fed. Reg. 5378 (Feb. 3, 2003) (proposed 21 C.F.R. § 1.243). That proposal further states that FDA will disclose confidential information to other governments only in the event of an emergency, provided that it first obtains written assurance from the recipient that the information will remain confidential. Our recommendation is that the FDA include similar restrictions on the use of product identity information in its prior import notice rule to those found in the food facility registration proposal.

2. Liable party. The proposed rule provides that any person who imports, or offers for import, an article of food without complying with section 801(m) of the FDC Act (i.e., the prior import notice provisions), or any person who causes such violation, is potentially subject to a civil injunction suit or a criminal action brought by the U.S. See 68 Fed. Reg. at 5461 (proposed 21 C.F.R. § 1.278(g)).

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Nutraceutical requests clarification of this provision as it applies to the party responsible for submitting the prior import notice.

FDA's proposal provides that the "purchaser or importer of an article of food who resides or maintains a place of business in the United States" is the party authorized to submit a prior notice. See 68 Fed. Reg. at 5432 (proposed 21 C.F.R. § 1.285). FDA also proposes that a U.S. agent with a residence or place of business in the U.S., or a customs broker that is the U.S. agent of the U.S. importer or purchaser, may submit a prior notice on behalf of the U.S. purchaser or importer. Id.

In the event that the purchaser or importer contracts with its U.S. agent to assume the responsibility for submitting prior notices, does FDA contemplate that there will (or recommend that there should) be a written agreement between or among the parties that clearly delineates these duties, as with the registration proposal? Assuming that such an agreement exists, if the U.S. broker failed to submit a required prior notice, and the FDA decided to exercise its enforcement authority, would the purchaser/importer be held liable? If so, which employee or officer would be liable in the case of a corporation that had retained the importer? Presumably, the language of the proposed regulation is broad enough to cover both the purchaser/importer and its U.S. agent and potentially their employees. How will FDA decide which party is liable, or will it hold both parties liable? Furthermore, the proposed rule seems to suggest that if the prior import notice is merely "inadequate" that this may result in criminal liability. Nutraceutical believes that clarification of these issues is of critical importance in light of the potential for a criminal action against the violative party.

3. Single amendment. In the interest of facilitating the efficient use of agency resources, FDA has proposed that a party wishing to amend its prior notice do so only once. However, given the range of consequences for failure to submit an adequate prior notice for an article of imported food – from economic losses to, as discussed above, criminal penalties – Nutraceutical believes that it is unreasonable to limit the number of permissible amendments to one amendment per prior notice. If the purpose of the prior notice rule is to ensure that FDA receives accurate information about incoming shipments to enable the agency to, among other things, take precautionary measures in the event of an emergency, such a limitation would also be ill-advised because it might undermine this goal. Given the potential magnitude of these penalties for importers and other parties who are authorized to file prior notices, parties should be given the opportunity to amend as many times as is necessary to ensure the accuracy of the information.

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Nutraceutical appreciates the opportunity to comment on this proposed rule.

Sincerely,

NUTRACEUTICAL CORPORAITON

Stanley E. Soper,
Vice President, Legal Affairs